DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 6, 2014

Bio Compression Systems, Inc.
Barbara Whitman
Director, RA & QA
120 West Commercial Ave.
Moonachie, New Jersey 07074

Re: K142640
Trade/Device Name: Model SC-3004-DL Sequential Circulator, Model SC-3004FC-DL Sequential Circulator, Model SC-2008-DL Sequential Circulator, Model SC-3008-DL Sequential Circulator
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: September 16, 2014
Received: September 17, 2014

Dear Ms. Whitman,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

I. Indications for Use Statement

510(k) Number: Unknown K142640

Device Names: Bio Compression Systems Sequential Circulator digital series model numbers SC-3008-DL, SC-3004-DL, SC-3004FC-DL and SC-2008-DL.

Indications for Use:
The Bio Compression Systems' SC-3008-DL, SC-3004-DL, SC-3004FC-DL and SC-2008-DL pumps and associated garments are sequential, pneumatic compression devices intended for the primary or adjunctive treatment of primary or secondary lymphedema. These devices are also intended for the additional or alternate treatment of venous insufficiency and chronic venous stasis ulcers associated with venous insufficiency, as well as general treatment for swelling of the extremities. The devices are intended for home or hospital use.

Prescription Use (Part 21 CFR 801 Subpart D)	___X____	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)	_____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

II. 510(k) Summary

APPLICANT'S INFORMATION:
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SUBMITTER'S INFORMATION
Same as Applicant

DATE: September 16, 2014

DEVICE INFORMATION

DEVICE NAME:	SC-3008-DL Sequential Circulator SC-3004-DL Sequential Circulator SC-3004FC-DL Sequential Circulator SC-2008-DL Sequential Circulator
Classification Panel:	Cardiovascular and Respiratory Devices
Classification Number:	870.5800
Product Nomenclature:	Compressible Limb Sleeve
Product Code:	JOW
Trade/Proprietary Name:	SC-3008-DL, SC-3004-DL, SC-3004FC-DL, SC-2008-DL Sequential Circulators
Common Name:	SC-3008-DL, SC-3004-DL, SC-3004FC-DL, SC-2008-DL Sequential Circulators

DEVICE CLASSIFICATION
Compressible Limb Sleeve Devices are classified as Class II devices, and reviewed by the Division of Cardiovascular and Respiratory Devices.

PREDICATE DEVICE
The predicate device is the SC-3008 Sequential Circulator, K043423

DEVICE DESCRIPTION
The devices consist of AC-powered pumps and inflatable garments connected by flexible tubing. The pumps consist of a compressor capable of a maximum pressure of 150 mmHg, a rotating disc valve driven by a motor and a digital pressure sensor, housed in durable plastic. Moving parts are not accessible to the user. The garments consist of four (SC-3004-DL and SC-3004FC-DL) or eight (SC-2008-DL and SC-3008-DL) discrete inflatable chambers, attached to the pump via tubing, and are applied externally over the affected limb or torso. Unilateral or bilateral limb treatment can be applied. Unique connector fittings on the tubing prevent accidental and incorrect pump/garment combinations or use with garments or sleeves from other manufacturers.

The system provides gradient pressurization to the chambers, i.e., sequential inflation of distal to proximal, with distal chambers inflated to a greater pressure than the proximal ones. As each chamber is inflated, the pressure is held constant until all chambers are inflated, in order to prevent reverse gradient flow. Once all chambers are inflated, the pressure is released in all chambers simultaneously, and the cycle repeats. The SC-3004-DL provides a 90-second inflation/deflation cycle, while the SC-3008-DL, SC-2008-DL and SC-3004FC-DL models provide 50-second cycles. The SC-3004FC-DL model is "fast cycle" and use the faster (8-chamber device) motor to turn the valve, providing faster cycle times for the four-chamber models.

Operating pressure is 30 to 120 mmHg. Pressure is pre-set at the factory to 60 mmHg (distal) with a decreasing distal-to-proximal gradient of 1 mmHg per chamber. The compressor is capable of no more than 150 mmHg pressure, making the device intrinsically safe. Pressure can be adjusted up or down in increments of 1 mmHg with the UP and DOWN pressure button arrows. The pressure is regulated by a digital pressure sensor that turns the air compressor pump on and off according to the pump pressure setting, and an LED panel displays the set pressure and displays "0" during the deflation cycle. In the SC-2008-DL device, the UP and DOWN pressure buttons allow the user to change the pressure in the distal chamber, and the decreasing 1 mmHg/chamber gradient is maintained throughout the remaining chambers. The SC-3004-DL, SC-3004FC-DL and SC-3008-DL models have the same feature but additionally provide a means to change the individual chamber pressures in the gradient. The software prevents reverse gradient adjustments.

When the garments are inflated, they compress the limb and help to move lymph away from the extremities and/or torso so it can be eliminated by the body. Garments are available in sizes to accommodate varying limb lengths and girth, and custom garments can be provided. The SC-3004-DL and SC-3004FC-DL systems have four-chamber garments, and the SC-2008-DL and SC-3008-DL systems have eight-chamber garments. Garments are supplied non-sterile, intended for single patient use, and are intended to be applied over bandages or clean hosiery. Velcro fasteners support garment application. Instructions are provided for the patient to attach the garments and perform therapy at home after a physician has prescribed treatment and the patient has been oriented and educated on proper use of the device.

The user interface consists of UP and DOWN pressure adjustment arrows (buttons). All controls and measurement functions are integrated into the PCB assembly. When turned on, the timer sends a signal to start the pump and the valve motor. The pump sends air through the valve, which turns and sends air to the output ports, filling each garment chamber sequentially. As the valve continues to rotate the air is released from all chambers at once and the garment deflates. The cycle repeats every 90 seconds for the SC-3004-DL or every 50 seconds for the SC-2008-DL, SC-3008-DL and 3004FC-DL. Treatment duration is prescribed by the physician, and typically is two one-hour sessions per day.

INDICATIONS FOR USE

The Bio Compression Systems' SC-3008-DL, SC-3004-DL, SC-3004FC-DL and SC-2008-DL pumps and associated garments are sequential, pneumatic compression devices intended for the primary or adjunctive treatment of primary or secondary lymphedema. These devices are also intended for the additional or alternate treatment of venous insufficiency and chronic venous stasis ulcers associated with venous insufficiency, as well as general treatment for swelling of the extremities. The devices are intended for home or hospital use.

TECHNOLOGICAL CHARACTERISTICS

The manufacturer believes that the technological characteristics of the modified (digital) SC-3008-DL, SC-3004-DL, SC-3004FC-DL and SC-2008-DL Sequential Circulators are substantially similar to those of the predicate (analogue) device. The user interface has been modified from a rocker on/off switch, pressure-control dial and analogue needle pressure gauge in the predicate device to pressure contact buttons and an LED display in the applicant devices. In place of a manual adjustment dial on the regulator in the predicate device, the pressure can be increased or decreased in increments of 1 mmHg via the UP and DOWN pressure buttons on the applicant devices.

PERFORMANCE DATA

Before being released every device is tested and must meet all performance specifications. In addition to aesthetic acceptance criteria, functional testing includes electrical leakage, pressure adjustment, inflation pressure in each chamber, air pressure display accuracy, and inflation/deflation cycle times. The results demonstrate comparable inflation cycle profiles (rise times, inflation pressures, deflation times and cycle times) between the applicant and predicate devices.

STATEMENT OF SUBSTANTIAL EQUIVALENCE

Similarities

Both the applicant and the predicate devices provide sequential inflation pressure from distal to proximal chambers and have the same intended use and indications for use and all devices operate within the same clinically-established parameters. Both the applicant and predicate devices offer adjustable pressure ranges. The predicate device is an eight-chamber system, and the SC-2008-DL and SC-3008-DL are also eight chamber systems and use the same garments. The applicant and predicate devices use the same prescribed inflation pressures, inflation and deflation times and have an internal one-hour timer for treatment duration.

Differences

The applicant devices are controlled via a PCB that includes a digital pressure sensor and LED pressure display, while the predicate device utilizes an analogue needle gauge display. The applicant devices have up and down pressure contact buttons (arrows) to adjust pressure up or down, while the predicate has a locking pressure control knob attached to a regulator. In the predicate device, the individual gradient pressures are adjusted by screws on the bottom of the pump, while on the applicant devices, gradient pressures are adjusted using the pressure UP/DOWN arrows after entering an access sequence on the contact pressure buttons. (Note: only the SC-2008-DL does not have an option for adjusting the individual gradient pressures.)

The predicate device is an eight-chamber system, while the SC-3004-DL and SC-3004FC-DL are four-chamber systems and use four-chamber garments.

The predicate device has a replaceable fuse, which is accessible by the user, while the applicant devices have internal fuses that are not user-accessible. The applicant SC-3008-DL has a "Pretreatment Mode" option, where the three most proximal chambers will cycle for 10 minutes prior to engaging all eight chambers. This mode is thought to mimic manual massage and help relieve congestion in the proximal areas, thus facilitating the movement of lymph in the more distal areas. The predicate device and the SC-3004-DL, SC-3004FC-DL and SC-2008-DL do not have a Pretreatment Mode option. The applicant devices have a continuous mode option, while the predicate device does not have a continuous mode option and must be turned off manually.

The differences between the predicate and the applicant devices do not impact safety or effectiveness. A table illustrating the similarities and differences is provided below:

Table of Similarities and Differences with the Predicate Device

Parameter	SC-3008-DL	SC-3004-DL	SC-3004FC-DL	SC-2008-DL	Predicate SC-3008
Intended Use	Intended for the primary or adjunctive treatment of primary or secondary lymphedema. Also intended for the additional or alternate treatment of venous insufficiency, and chronic venous stasis ulcers associated with venous insufficiency, as well as general treatment for swelling of the extremities. For home or hospital use.				
Principal of Operation	Sequential pneumatic compression				
Weight	5.5 pounds	5.5 pounds	5.5 pounds	5.5 pounds	8 pounds
Dimensions, inches	4.5H x 11.75W x 7.75D	4.5H x 11.75W x 7.75D	4.5H x 11.75W x 7.75D	4.5H x 11.75W x 7.75D	5.5H x 12W x 8D
# of Chambers in garment	8	4	4	8	8
Sequential chamber inflation	Yes				
Distal/Proximal gradient	Yes				
Pressure adjustment	Pressure Buttons, mmHg, digital				Analogue dial and regulator
Pressure Control	Solenoid			Compressor on/off cycles	Regulator
Pressure Gauge	Digital, three-digit mmHg LED panel				0-125 mmHg Analogue
Inflation Pressure	30 - 125 mmHg distal, adjustable in 1 mmHg increments				
Inflation Time, each chamber	5.5 seconds	18 seconds	5.5 seconds	5.5 seconds	5.5 seconds
Deflation Time (All chambers simultaneously)	5.5 seconds	18 seconds	5.5 seconds	5.5 seconds	5.5 seconds
Total Cycle Time	50 seconds	90 seconds	50 seconds	50 seconds	50 seconds
Garments Available	8 chamber arm/leg/torso	4 chamber arm/leg/torso	4 chamber arm/leg/torso	8 chamber arm/leg/torso	8 chamber arm/leg/torso
Fail-safe hose connectors	Yes				
Uni/Bilateral Use	Yes				
On-board 1 hour session timer	Yes				
Pretreatment Mode	Yes	No	No	No	No
Logs Total Use Hours	Yes	Yes	Yes	Yes	No
Replaceable Outer Fuse	No	No	No	No	Yes
Power Source	115VAC, 50-60Hz				

CONCLUSION

There is no change in fundamental technology between the SC-3008-DL, SC-3004-DL, SC-3004FC-DL and SC-2008-DL Sequential Circulators and the predicate device. Based upon safety and performance testing, compliance with voluntary standards, and comparison to the predicate device, the manufacturer believes that the SC-3008-DL, SC-3004-DL, SC-3004FC-DL and SC-2008-DL Sequential Circulators are substantially equivalent to the predicate device, and do not raise any new questions of safety or effectiveness.